

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
JAN-27

APPLICATION
NO. 10/625,754
~~10/008,516~~
10/008,516

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICANT
Leventer et al.

CONFIRMATION NO.
Not yet assigned

FILING DATE
11/8/01

GROUP Not yet assigned

FEB 26 2002

RECEIVED

U.S. PATENT DOCUMENTS

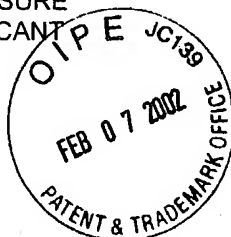
[illegible]

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
JAN-27APPLICATION
NO. 10/625,754
~~40/008,546~~INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Leventer et al.CONFIRMATION NO.
Not yet assignedFILING DATE
11/8/01GROUP
~~Not yet~~
assigned
16/4

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
<u>PTO</u>	S. Almquist et al., "Direct and Indirect Approaches to Enantiomeric Separation of Benzodiazepines Using Micro Column Techniques," <i>J. Chromatography A</i> , 679:139-146 (1994).
<u>25</u>	
<u>26</u>	N. Bargmann-Leyder et al., "A Comparison of LC and SFC for Cellulose- and Amylose-Derived Chiral Stationary Phases," <i>Chirality</i> , 7:311-325 (1995).
<u>27</u>	A. Bond and M. Lader, "A Comparison of the Psychotropic Profiles of Tofisopam and Diazepam," <i>Eur. J. Clin. Pharmacol.</i> , 22:137-142 (1982).
<u>28</u>	M. Briley et al., "Tofisopam Enhances the Anticonvulsant Activity of Diazepam Against Some, but Not All, Convulsive Agents," <i>British J. Pharm.</i> , 82:300P (1984).
<u>29</u>	G. De Sarro et al., "GYKI 52466 and Related 2,3-benzodiazepines as Anticonvulsant Agents in DBA/2 Mice," <i>Eur. J. Pharmacol.</i> , 294:411-422 (1995).
<u>30</u>	I. Fellegvári et al., "Separation of Conformational Diastereomers of 2,3-Benzodiazepines by HPLC," <i>Chromatography in Symposia Biologica Hungarica</i> , H. Kalász and L.S. Ettre, Eds., 193-203 (1987).
<u>31</u>	V. Filip et al., "A Double-Blind, Placebo-Controlled Study with Tofizopam in Anxiety Neurosis," <i>Agressologie</i> , 22:27-30 (1981).
<u>32</u>	I. Fitos et al., "Separation of Enantiomers of Benzodiazepines on the Chiral-AGP Column," <i>J. Chromatography A</i> , 709:265-273 (1995).
<u>33</u>	E. Fogassy et al., "Studies on the Properties and Structure of Optically Active 1-(3,4-Dimethoxyphenyl)-4-Methyl-5-Ethyl-7,8-Dimethoxy-5H-2,3-Benzodiazepine (Tofizopam)," in <i>Bio-Organic Heterocycles</i> , H.C. van der Plas, L. Ötvös, and M. Simonyi, Eds., 229-233 (1984).
<u>34</u>	H. Goldberg et al., "Comparative Efficacy of Tofisopam and Placebo," <i>Am. J. Psychiatry</i> , 136:196-199 (1979).
<u>35</u>	K. Imre et al., "A Tofizopam (Grandaxin®) Farmakokinetikaja es Metabolizmusa," <i>Acta Pharmaceutica Hungarica</i> , 63:83-90 (1993).
<u>36</u>	C. Ito, "Behavioral Pharmacological Study on the Structure Activity Relationship of Benzodiazepine Derivatives: with Particular Reference to the Activity of 2,3-Benzodiazepine," <i>J. Tokyo Med. College</i> , 39:369-384 (1981).
<u>37</u>	J. Kanto et al., "Tofizopam: a Benzodiazepine Derivative without Sedative Effect," <i>Intl. J. Clin. Pharm. Ther. Tox.</i> , 20:309-312 (1982).
<u>38</u>	K. Maier et al., "The Effect of Tofisopam on Psychic Performance in Persons With More Than Average Anxiety: A Controlled Experimental Trial," <i>Current Therapeutic Research</i> , 35(4):541-548 (1984).
<u>PTO</u>	"Tofisopam", Martindale, Royal Pharmaceutical Society of Great Britain, p. 620, col. 1 (1993).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered; whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
JAN-27APPLICATION
NO. 10/625,754
~~10/000,516~~INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Leventer et al.CONFIRMATION NO.
Not yet assignedFILING DATE
11/8/01GROUP
~~Not yet assigned~~
1614

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
C70 37	T. Mennini et al., "Brain Levels of Tofisopam in the Rat and Relationship with Benzodiazepine Receptors," <u>Arch. Pharmacol.</u> , 321:112-115 (1982).
40	J. Molcan et al., "Tofizopam in the Therapy of Anxious-Depressive Syndroms," <u>Agressologie</u> , 22:23-24 (1981).
41	F. Pal, "A Grandaxin® Gyógyszertechnológiája," <u>Acta Pharmaceutica Hungarica</u> , 63:67-78 (1993).
42	Pakkanen et al., "Comparative Study of the Clinical Effects of Tofizopam, Nitrazepam and Placebo as Oral Premedication," <u>British J. Anaesthesia</u> , 1009-1012 (1980).
43	S. Pellow and S. File, "The Effects of Tofisopam, a 3,4-Benzodiazepine, in Animal Models of Anxiety, Sedation, and Convulsions," <u>Drug Dev. Res.</u> , 7:61-73 (1986).
44	L. Petőcz and I. Kosóczy, "The Main Pharmacological Characteristics of Grandaxin (Tofisopam, EGYT-341)," <u>Ther. Hungarica</u> , 23:134-138 (1975).
45	L. Petőcz, "The Pharmacological Effects of Tofisopam (Grandaxin®)," <u>Acta Pharmaceutica Hungarica</u> , 63:79-82 (1993).
46	V. Saano and A. Urtti, "Tofizopam Modulates the Affinity of Benzodiazepine Receptors in the Rat Brain," <u>Pharm. Biochem. Behavior</u> , 17:367-369 (1982).
47	V. Saano, "Tofisopam Selectively Increases the Action of Anticonvulsants," <u>Med. Biol.</u> , 64:201-206 (1986).
48	V. Saano et al., "Tofisopam Enhances the Action of Diazepam Against Tremor and Convulsions," <u>Med. Biol.</u> , 61:49-53 (1983).
49	T. Seppälä et al., "Tofisopam, a Novel 3,4-Benzodiazepine: Multiple-Dose Effects on Psychomotor Skills and Memory. Comparison with Diazepam and Interactions with Ethanol," <u>Psychopharmacology</u> , 69:209-218 (1980).
50	M. Simonyi and I. Fitos, "Stereoselective Binding of a 2,3-Benzodiazepine to Human Serum Albumin," <u>Biochemical Pharmacology</u> , 32(12):1917-1920 (1993).
51	R. Sladká et al., "A Placebo-controlled Clinical Trial With Tofizopam in the Treatment of Anxiety Neurosis," <u>Ther. Hungarica</u> , 27:176-180 (1979).
C70 52	J. Szegő et al., "Selected Passages From the Clinical-Pharmacological and Clinical Trials of Grandaxin®," <u>Acta Pharmaceutica Hungarica</u> , 63:91-98 (1993).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
JAN-27APPLICATION
NO. 10/625,754
~~10/008,516~~INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Leventer et al.CONFIRMATION NO.
Not yet assignedFILING DATE
11/8/01GROUP
Not yet assigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
<i>CTD</i> 53	G. Toth et al., "Racemate Splitting of (+)-5-ethyl-1-(3,4-dimethoxyphenyl)-6,7-dimethoxy-4-methyl-5H-2,3-benzodiazepine an Anomalous Chiroptic Behavior of Enantiomer (1)," <u>J. Heterocyclic Chem.</u> , 20:709-713 (1983).
<i>54</i>	G. Várady et al., "The Clinical Evaluation of Grandaxin Used in the Treatment of Outpatients (A Multicentric Study)," <u>Ther. Hungarica</u> , 23:153-158 (1975).
<i>55</i>	J. Visy and M. Simonyi, "The Role of Configuration and Conformation in the Binding of 2,3-Benzodiazepines to Human Serum Albumin," <u>Chirality</u> , 1:271-275 (1989).
<i>CTD</i> 56	F. Zsila et al., "Separation and Identification of Tofisopam and Stereoisomers by Hyphenated HPLC-CD Technique," <u>J. Liq. Chrom. & Rel. Technol.</u> , 22:713-719 (1999).

EXAMINER

DATE CONSIDERED

8/4/04

11/2/03

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.